Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

510(k) Summary

DEC 18 2012

Submitter:	ColoplastA/S Holtdam 1 3050 Humelbaek, Denmark Establishing Registration: 9610694 Owner/Operator: 8010144
Contact:	Janell Colley 1601 West River Road Minneapolis, MN 55411 Office: 612-344-2334 Fax: 612-287-4138
Date Prepared:	December 17, 2012
Trade Name:	NovaSilk Mesh
Common Name:	Surgical Mesh
Classification:	II
Product Code:	OTO-Mesh, Surgical, Gynecological, for Apical Vaginal Prolapse, Transabdominally Placed
Regulation:	21 CFR 878.3300
Panel:	Obstetrics/Gynecology
Predicate Devices:	NovaSilk Mesh, Coloplast (K053414) cleared 12/27/2005 Vertessa, Caldera Medical (K120327) cleared 5/10/2012

Device Description:

NovaSilk Mesh is an implantable, permanent, non-resorbable, synthetic support mesh manufactured from knitted, monofilament polypropylene. It is square in shape, measuring 150mm x 150mm, and 0.25mm thick.

Intended Use:

NovaSilk Mesh is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Predicate Device Comparison:

The technological characteristics of NovaSilk Mesh (subject device) are identical to NovaSilk Mesh (K053414, predicate device). NovaSilk Mesh (subject device) has narrower indications for use than NovaSilk Mesh (K053414, predicate device). The fundamental scientific technology has not changed from the predicate device to the subject device. NovaSilk Mesh (subject device) also has similar materials and indications for use as Vertessa (K120327, predicate device).

Performance Data Summary:

Design verification, biocompatibility, sterilization, and shelf life testing completed on the predicate Novasilk Mesh confirm the subject device meets the established design specifications and is substantially equivalent to the predicate.

Conclusions:

NovaSilk Mesh is substantially equivalent to the proposed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2012

Coloplast Corp.
% Ms. Janell Colley
Regulatory Affairs Manager
1601 West River Road North
MINNEAPOLIS MN 55411

Re: K122968
Trade/Device Name: NovaSilk Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: September 24, 2012
Received: September 25, 2012

Dear Ms. Colley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5 Statement of Indications for Use

510(k) Number (if known): K122968

Device Name: NovaSilk Mesh

Indications for Use:

NovaSilk Mesh is indicated for use as a bridging material for sacrocolposuspension/ sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment of vaginal vault prolapse is warranted.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122968